K011622

510(k) Summary: T2 Locking Screws – Use with Osteo Femoral and Tibial Nails

Submission Information

Name and Address of the Sponsor of the 510(k) Submission:	Howmedica Osteonics Corp 59 Route 17 Allendale, NJ 07401-1677
Contact Person:	Karen Ariemma Regulatory Affairs Specialist
Date of Summary Preparation:	May 24, 2001

Device Identification

Proprietary Name:	Osteo IC Femoral and Tibial Nails and Osteo Retrograde/Antegrade Femoral Nails with T2 Locking Screws
Common Name:	Intramedullary Nails
Classification Name and Reference:	Intramedullary Fixation Rod, 21 CFR §888.3020

Predicate Device Identification

The Osteo IC Femoral and Tibial Nails (K992063) and Osteo Retrograde/Antegrade (R/A) Femoral Nails (K982601) have been determined Substantially Equivalent when used with associated Osteo IC 5.0mm diameter Locking Screws. The T2 Femoral Nails (K010801) and T2 Tibial Nails (K003018) have also been determined Substantially Equivalent when used with associated T2 5.0mm diameter Locking Screws. This submission is intended to allow use of the predicate 5.0mm diameter T2 Locking Screws with the predicate Osteo IC Femoral/Tibial Nails and Osteo R/A Femoral Nails.

Description of Device Modification

This submission involves no change to the components themselves. This submission covers use of predicate T2 Locking Screws with predicate Osteo IC Femoral/Tibial Nail and Osteo R/A Femoral Nail Systems.

Intended Use

The T2 Locking Screws continue to be intended for single use only. They are intended for use with the predicate Osteo IC Femoral/Tibial Nail and Osteo R/A Nail Systems and, when used with these nail systems, are subject to their specific indications.

Statement of Technological Comparison:

The T2 Locking Screws are identical in materials and are similar in design to the associated locking screws originally cleared for use with the specified Osteo Nail Systems. Engineering analysis and testing have shown that the T2 Locking Screws are similar enough to the Osteo Locking Screws to be safely used with the associated Osteo IC Femoral/Tibial Nail and Osteo R/A Femoral Nail Systems

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 5 2001

Ms. Karen Ariemma
Regulatory Affairs Specialist
Howmedica Osteonics Corporation
59 Route 17
Allendale, New Jersey 07401-1677

Re: K011622
Trade Name: Osteo IC Femoral and Tibial Nails and Osteo Retrograde/Antegrade
Regulatory Number: 888.3020
Regulatory Class: II
Product Code: HSB
Dated: May 24, 2001
Received: May 25, 2001

Dear Ms. Ariemma:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., ~~M.D.~~
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 011622

Device Name: T2 Locking Screws – Use with Osteo Femoral and Tibial Nails

The T2 Locking Screws continue to be intended for single use only. They are intended for use with the predicate Osteo IC Femoral/Tibial Nail and Osteo R/A Nail Systems and, when used with these nail systems, are subject to their specific indications.

Indications for the T2 Locking Screws when used with Osteo IC Femoral and Tibial Nails (K992063):

- Open and closed femoral and tibial shaft fractures
- Pseudoarthrosis and correction osteotomies
- Pathologic fractures and tumor resections
- Change of procedure following external fixation

Indications for the T2 Locking Screws when used with Osteo R/A Femoral Nails (K982601):

The Osteo R/A Femoral Nail is indicated for long bone fracture fixation, specifically femoral fracture fixation, which may include the following:

- Open and closed femoral fractures
- Pseudoarthrosis and correction osteotomy
- Pathologic fractures, impending pathologic fractures, and tumor resections
- Supracondylar fractures, including those with intra-articular extension
- Ipsilateral femur fractures
- Fractures proximal to a total knee arthroplasty
- Fractures distal to a hip implant
- Nonunions and malunions

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number 011622